Major aspects of the panel discussion

# “The Future for Occupational Safety and Health in Biocide Regulations”

on the second day – April 4th 2006 – of the workshop

# “Occupational Safety and Health during the Use of Biocides”

Chairman:
Reiner Arndt (BAuA, Germany)

On the Panel:
Kirsten Rasmussen (ECB, European Union)
Sabine Darschnik (BAuA, Germany)
Joop van Hemmen (TNO, Netherlands)
Stephen Kinghorn-Perry (HSE, UK)

Reiner Arndt introduced the panel and asked the participants to start the panel discussion with some short statements.

Kirsten Rasmussen stated that this workshop was just the opening for a more intense discussion in the future that is necessary for a common understanding between the member states. This understanding is a requirement for minimising the work input and maximising the harmonisation which is necessary to enable the mutual recognition of authorisations for biocidal products.

Joop van Hemmen pointed out that this workshop could be a starting point for other more specialised discussion groups in which the member states can learn from each other how to do things more similar that have been done dissimilar in the past. A harmonisation might not be mandatory but the experiences collected in the first dossiers have to be saved and made available systematically to all persons involved in exposure assessment.

Sabine Darschnik raised the question what the major issues of occupational safety and health in the biocides processes would be in the future. She also asked the audience for ideas to identify these issues. One way forward could be to collect the information already available without too much effort.

Stephen Kinghorn-Perry clarified that there are right now so many questions that it is even a problem to find the key-questions to undertake an appropriate exposure assessment. On the other hand already now the danger exists that discussions do not lead to results. He suggests to use all available tools for exposure assessment (including models and data collection) reveal whether these tools work and decide after some time of learning which tool works best for which situation.

The following discussion on the panel and with the audience concentrated on several aspects which were discussed already during the workshop, were addressed by presentations or within in the “thought starters for further discussions” before the panel discussion. The major aspects and the results of the discussion are:

**Exposure Assessment**

The experience from the first dossiers illustrates that for exposure assessment the available guidance (TNsG Human Exposure, worked examples of the user guidance group for wood preservatives and rodenticides) is not sufficient for an efficient and harmonised (between different member states) evaluation. Therefore the available information from the different CA-reports should be collected and discussed in a smaller, more specialised group to learn from the work performed already and by this to develop a broader understanding for the future work within the review-programme and the authorisation-process.
Joop van Hemmen offered to initiate an expert group for this purpose but further discussion and co-ordination are necessary within TNO, the Netherlands and potential members of this group.

The role of workplace monitoring and measurements of inhalation exposure was discussed as a tool for industry (proof of safe handling, product stewardship) and the authorities (tier 3 of the exposure assessment, requirement for authorisation). This legally – also for biocidal products –

available tool is used broadly in authorisation processes of plant protection products but is not used for biocidal products, yet. Industry usually wants to avoid the costs of those studies and the desire to co-operate and share data competes against the wish of data protection. Therefore it is unclear if those exposure studies will be more common in the future. In order to overcome these obstacles it might be necessary for the authorities to identify certain gaps in knowledge whose bridging would be helpful for several product types or at least several active substances within one product type. Under those conditions the advantages might outweigh the efforts and industry might be willing to co-operate.

It is necessary, in any case, to find a compromise between the scientifically correct assessment of exposure which is easier with measurements and the necessity of keeping a number of active substances on the market which would be made more difficult by too high demands on exposure studies.

The hope was expressed by several participants of the workshop that the ongoing EU-project on human exposure which is conducted by TNO and supported by HSE and BAuA will harmonise or standardise the evaluation of workplace exposure by robust worked examples. It was also stated that even a revised and evolved TNsG still is not a fixed standard for exposure assessment but needs to be open for new information, models and data. Therefore the development of exposure assessment is an ongoing process.

**Coexistence of Different Approaches for Risk Assessment**

A thought starter “Suggestions for Harmonisation of Reference Values” was presented by the German assessment unit for biocides at the workplace. It was generally agreed that using different systems for evaluating the same data can lead to confusion and misunderstandings. The problem becomes obvious, if the AOEL derived under the Biocidal Directive considerably differs from an occupational exposure limit value (OEL) proposed by SCOEL. However, further experience from the evaluation of substances seems to be needed to identify a promising way forward.

In this context Kirsten Rasmussen clarified that it was agreed and laid down in TNsG’s to use both, the AOEL and the MOE approach for risk characterisation during an initial testing period. After that

it should be possible to decide which approach provides the better results for the risk assessment of biocides by comparing the results.

Sabine Darschnik pointed out, however, that the presently available dossiers do not offer a fair comparison between MOE and AOEL and therefore no decision is to be expected on that basis about the quality of results for the different approaches.

As one possible way forward the idea of a tiered procedure was proposed:
Since the AOEL approach is assumed to represent the most conservative and protective methodology it can be used in a first step to identify those use scenarios for biocidal products which potentially are associated with risks. Use scenarios without concern at this step do not need further consideration.
In the second tier concern scenarios from the first step shall be assessed more thoroughly by applying specific instruments of occupational safety and health like the MOS approach, inhalative OEL or reference values for dermal exposure. By this not only the exposure assessment but the whole risk assessment will be continually improved in a stepwise procedure.
Reiner Arndt announced that this 2-step approach will be brought forward by the German assessment unit for the workplace to the Technical Meeting.

**Risk Management for Biocides**

One idea for risk management for biocides was the development of harmonised codes of good practise for the application of biocidal products. Examples were presented during the workshop that trained operators who use a good working practise can reduce the exposure by an order of magnitude compared to operators without good practise.
Harmonised codes could specify regulations on safety and health at work (instruction, training, exposure control, PPE) for the user and give a guidance for authorisation of biocidal products for the competent authorities and by this simplify the process of mutual recognition. On the other hand harmonisation on European level needs resources and the effect of this work has to outweigh the efforts.
For this topic nobody took the initiative to bring this forward to the Technical Meeting. It would be a starting point, though, to make available existing codes of good practise for biocides to other member states in English language. The German assessment unit for the workplace will consider if

it is possible to translate some important German codes of good practise. Those could be discussed on European level (for instruments for these discussions see below “exchange of information in the future”) and e.g. published on the homepage of the European Agency for Safety and Health at Work, Bilbao (http://osha.eu.int/OSHA).

Furthermore it is probable that with increasing experiences from CA-Reports more and more conditions for inclusion into Annex I will be developed and harmonised in a learning by doing process which will improve occupational safety and health. One aspect for example which would be helpful and which is already observable during dossier discussions and in the specific provisions for Annex I inclusion is the specification of training requirements for users of particular biocidal products.

**Exchange of Information in the Future**

Some member states undertake or plan research projects on exposure and occupational safety and health for the use of biocidal products. Reiner Arndt developed the idea during the workshop that it would be helpful to have some kind of central data collection which is available for interested persons. This data collection should make it possible to exchange information about ongoing or finished projects. By this it would be easier to use the limited resources for research more efficiently.
In order to start a data collection like this existing information about ongoing projects must be submitted by the institutions which do the research project in a specific format to enable a systematic search. Reiner Arndt pointed out that this format still needs to be developed and requires to contain at least the following points:

- Title of the project
- Aim of the project, major results
- Applied methodology of the project
- Contact person and institute

Kirsten Rasmussen offered that the ECB can administrate this data collection if the above outlined conditions are given. It is additionally possible to present the results of finished projects at Technical Meetings as it was already carried out for the Study “Human Exposure to Wood

Preservatives” which was undertaken by Austria and Germany. For this purpose at least a summary of the project results in English language is necessary.

Stephen Kinghorn-Perry made a suggestion about an electronic community of interest on human exposure assessments for biocides. He already progressed this idea and had a discussion within HSE. Essentially, it would be possible for HSE to 'host' such a web site which would be by invitation only. This would mean it could be concentrated on those people carrying out exposure assessments to biocides. Further discussion and co-ordination within HSE and potential members of the electronic network are necessary.

**Risk Assessment for Production and Formulation**

For years a source of controversies between member states, this topic was briefly discussed during the workshop and will be addressed at the Technical Meeting in June 2006 again. A paper is in preparation which is going to clarify the situation. As soon as it is agreed it shall be adopted by the Competent Authority Meeting.

**Next meeting**

It was agreed on by the participants of the workshop that it is desirable to meet again for discussion of occupational safety and health during application of biocides, notwithstanding the possibility or necessity for smaller more specialised meetings.
Reiner Arndt suggested to establish an organising committee consisting of representatives from two or three member states for a bigger meeting covering all aspects of occupational safety and health.
Joop van Hemmen offered to investigate the possibilities to organise a next workshop in 2007 in the Netherlands and asked for support and participation in the organisation. Interested persons might send him an email (vanHemmen@chemie.tno.nl) to signalise their interest. He also asks for contributions on topics for a next meeting.